K090238

510(k) Summary
510(k) Number K09

FEB 27 2009

Sedecal, Inc.
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Date Prepared: January 20, 2009
Contact: Mª Luisa Gómez de Agüero, Quality and Regulatory Manager

1. **Identification of the Device:**
   Proprietary-Trade Name: Sedecal X-Plus LP Plus Digital Diagnostic X-Ray System
   Classification Name: Stationary x-ray system, Product Code 90 KPR and Solid State X-Ray Imager (Flat Panel/Digital Imager) 90 MQB,
   Common/Usual Name: Digital Stationary Diagnostic X-Ray System

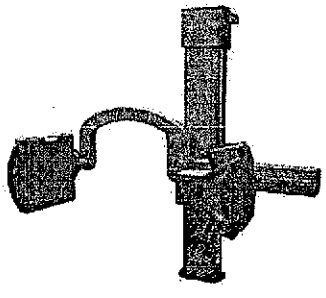
2. **Equivalent legally marketed device**: Sedecal URS LP Digital K042876 and Sedecal X Plus LP Plus, K062335. Digital panels: Canon, K060433 (50C); K031633 (40C); K031447 (50G); K023750 (40G).

3. **Indications for Use (intended use)** These Digital Radiographic Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

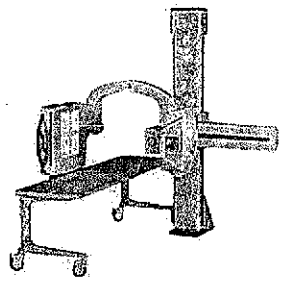
4. **Description of the Device**: These digital diagnostic x-ray systems consist of a tubehead/collimator assembly mounted on a U-Arm, along with a generator, generator control, and an x-ray table. Power ratings for the available generators are in the rage of 50 kw to 80 kW. Exposure voltage range varies from 40 – 125 KV or 40 – 150 kV with current of 300 – 100 mA. Exposure time is 1 ms – 10 s. This device represents a new combination of already cleared Sedecal and Canon products.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and test laboratory indicates that the new device is as safe and effective as the predicate devices.

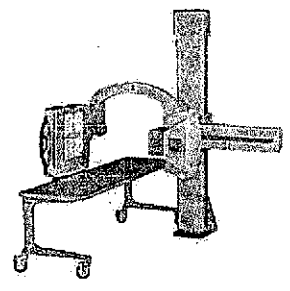
URS LP Digital, K042876



Sedecal X Plus LP Plus K062335



Sedecal X Plus LP Plus Digital



6. Substantial Equivalence Chart

Characteristic	Sedecal URS LP Digital, K042876	Sedecal X Plus LP Plus, K062335.	Sedecal X-Plus LP Plus Digital
Intended Use:	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	SAME	SAME
Configuration	U-Arm mount or Ceiling Suspension	U-Arm mount only	U-Arm mount only
Positioning controls	Standard	Enhanced	Enhanced, same as X Plus LP Plus
Performance Standard	21 CFR 1020.30	SAME	SAME
Generator	High frequency made by Sedecal	SAME	SAME
Collimator	Manual, Ralco	Manual, Ralco	Manual (Ralco) or Automatic (Huestis)
Image acquisition	Digital CANON 50G	Film	CANON panels, multiple models: 50C, 50G, 40C & 40G
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME	SAME

7. Conclusion

After analyzing bench and external laboratory testing to applicable standards, it is the conclusion of Sedecal Inc that the Sedecal X-Plus LP Plus Digital Diagnostic X-Ray Systems are as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2009

Sedecal SA
% Mr. Daniel Kamm, P. E.
Principal Consultant
Kamm & Associates
333 Milford Road
DEERFIELD IL 60015

Re: K090238
Trade/Device Name: Sedecal X-Plus LP Plus Digital Diagnostic X-Ray Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: January 30, 2009
Received: February 9, 2009

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090238

Device Name: Sedecal X-Plus LP Plus Digital Diagnostic X-Ray Systems

Indications For Use:

These Digital Radiographic Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090238